OIPE 449.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q86357

Tetsuro KIKUCHI, et al.

Appln. No.: 10/540,577

Group Art Unit: 1614

Confirmation No.: 6428

Examiner: Not Yet Assigned

Filed: June 24, 2005

For: CARBOSTYRIL DERIVATES AND SEROTONIN REUPTAKE INHIBITORS FOR

TREATMENT OF MOOD DISORDERS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicants hereby notify the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form which the Examiner may deem material to patentability of the claims of the above-identified application.

Additionally, Applicants wish to bring to the Examiner's attention the following two items of information which may be considered relevant to the examination of the present application:

 A particular form of the drug aripiprazole known as "Anhydrous Aripiprazole Crystals B" was approved by the Food and Drug Administration on November 15, 2002 and INFORMATION DISCLOSURE STATEMENT

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launched into the U.S. market after November 15, 2002 by a U.S. licensee of Otsuka

Pharmaceutical Co., Ltd.

(2) WO 03/026659 A1, a PCT international application assigned to Otsuka, discloses a process for preparing Anhydrous Aripiprazole Crystals B and was published April 3, 2003. A copy of WO 03/026659 A1 is submitted with this Information Disclosure Statement.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The attached Form PTO/SB/08 includes the four documents listed on the Search Report dated June 15, 2006 for the corresponding Georgian application. The non-U.S. patent documents have not yet been received from the Georgian associate. When received, they will be submitted to complete the record. In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicants enclose herewith a copy of the Search Report from the Georgian patent office in the counterpart Georgian application citing such documents, together with an English-language version of the report indicating the degree of relevance found by the foreign patent office.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicants do not

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waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted.

Brett S. Sylvester Registration No. 32,765

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23373 CUSTOMER NUMBER

Date: November 3, 2006

Substitute for Form 1449 A & B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

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Sheet	I	of	1

Comp	olete if Known			
Application Number	10/540,577			
Confirmation Number	6428			
Filing Date	June 24, 2005			
First Named Inventor	Tetsuro KIKUCHI			
Art Unit	1614			
Examiner Name				
Attorney Docket Number	O86357			

U.S. PATENT DOCUMENTS						
Examiner Cite	Cite	Document No		Publication Date		
Initials*	No.1	Number	Kind Code ² (if known)	MM-DD-YYYY Name of Patentee or Applicant of Cited		
/S.R.G.		US 60/319,436			Peter Migaly	
/S.R.G./		US 2004/0204401	Al	10-14-2004	Peter Migaly	
/S.R.G./		US 2002/0156067	Al	10-24-2002	Wong et al	
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FOREIGN PATENT DOCUMENTS							
Examiner	Cite	Foreign Patent Document		Publication Date	Name of Patentee or		
Initials*	No.1	Country Code ³	Number ⁴	Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Translation ⁶
/S.R.G./		wo	03026659		04-03-2003	Otsuka Pharmaceutical Co., Ltd.	
SRG/		RU	2181287	С	04-20-2002		
S.R.G./		RU	94037967	Al	08-27-1996		
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Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation
/S.R.G./		Lawler C. P. et al, "Interaction of the Novel Antipsychotic Aripiprazole (OPC-14597) with Dopamine and Serotonin Receptor Subtypes," Neuropsychopharmacology, 1999, Vol. 20, No. 6. pp. 612-627	
/S.R.G./		Copy of Georgian Search Report dated June 15, 2006	
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Examiner Signature /Shelley R. Graham/ Date Considered 01/23/2006	Examiner Signature		/Shellev R. Graham/	Date Considered	01/23/2008
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

^{*}Applicant's unsigne clustron designation number (optional). *See Kind Codes of USFTO Parent Documents at twew unpto, gov, MPEP 90.18 of (official) the hyperink from the like of the document to the internet. **Derco Office that is under the document, by the two-leter code (WPPO Standard ST. .) **To Japanese parent documents, the indication of the year of the reign of the Emperor must precede the resist number of the parent document. **Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. **Oppicant to it office here it English language Transition is naturaled.**